GE Healthcare

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Certified Mail Return Receipt Requested

URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

March 21, 2007

To:	**Director/Manager of Radiology** **Facility Administrator**
Subject:	**Product Safety Issues**
Affected Products:	**OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, and OEC® 9800MD Motorized C-arm System, OEC® 9900 Elite Fluoroscopy System, 9900 EliteMD Motorized C-arm System**

Our records indicate that your facility has one or more of the products listed above that are being used in conjunction with the four (4) pedal footswitch.

GE Healthcare has identified, through internal testing, the following potential safety issues that may occur with the four (4) pedal footswitch.

These issues include:

- Stalling on boot up.
- Grainy or washed out images
- "X-RAY SWITCH STUCK" error on boot up with and x-rays are not allowed.
- Image automatically saving if the footswitch is plugged in after system has booted.
- Saving during auto x-ray could cause the technique to go to maximum momentarily
- Mode button will not function.
- The third pedal takes an HLF shot instead of a Digital Cine shot and you could get an XRAY STUCK ERROR.

- Inability to take a Digital Cine shot
- Warning tone (beep) fails to activate

A GEHC Surgery field service engineer will be contacting your facility to remove the four (4) pedal footswitch and to install the appropriate 2 or 3 pedal footswitch.

Solution:

At this time GEHC Surgery will not be offering a replacement for the 4 pedal footswitch for use with the OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, and OEC® 9800MD Motorized C-arm System, OEC® 9900 Elite Fluoroscopy Systems, 9900 EliteMD Motorized C-arm System. Users will have the functionality previously available via the four (4) pedal footswitch by utilizing the 2 or 3 pedal footswitch combined with the hand switch.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
President and CEO